

REMARKS

Claims 1-40 will be pending in the instant application upon entry of this amendment. Claims 1-31 have been rejected. Claims 19-21 have been amended. Support for these amendments can be found in the specification on page 13, lines 16-28. New Claims 32-40 have been added. There is no new subject matter being added, and support for these claims can be found in the specification on page 14, lines 11-21.

Rejection of Claims 19-21 under 35 USC §112, first paragraph

The Examiner has rejected the specification under 35 USC §112, first paragraph, as not giving any guidance as to the full range of conditions which could be treated or prevented using the instant claimed process. Specifically, the Examiner stated that:

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 25 U.S.C. §112, first paragraph, have been described. They are: 1. nature of the invention, 2. the state of the prior art, 3. the predictability or lack thereof in the art, 4. the amount of direction or guidance present, 5. The presence or absence of working examples, 6. the breadth of the claims, 7. the quantity of experimentation needed, and 8. the level of skill in the art.

In the instant case, Applicants are claiming a method of preventing hot flashes, anxiety or depression. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles established that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant specification does not give any guidance as to how the instant claimed process effects the full range modalities and mechanisms necessary to completely prevent the conditions claimed i.e. more than one thing causes, for example, depression. In order to practice the claimed invention, one skilled in the art would have to speculate

which conditions could be prevented using the claimed compounds found in the instant claims. The number of possible conditions embraced by the claims would impose undue experimentation on the skilled art worker. Therefore the broad terminology treatment or prevention is not enabled because the metes and bounds of conditions that could be treated or prevented cannot be ascertained.

Applicants respectfully traverse the Examiner's rejection. However, in order to advance the prosecution of the present application, Applicants have deleted the reference to "prevention" in Claims 19-21. Thus, this rejection should be rendered moot.

Accordingly, Applicants respectfully request that the rejection of Claims 19-21 under 35 USC §112, first paragraph be withdrawn.

Rejection of Claims 19-21 under 35 USC §112, first paragraph

The Examiner has rejected the specification under 35 USC §112, first paragraph, on the grounds of insufficient utility. Specifically, the Examiner stated that:

While it is conceded that the claimed invention may have applicability for treatment of hot flashes, anxiety and depression, there is insufficient disclosure to support prevention of depression per se. Disclosure to support the full range modalities and mechanisms necessary to completely prevent depression is not given.

Applicants respectfully traverse the Examiner's rejection. However, in order to advance the prosecution of the present application, Applicants have deleted the reference to "prevention" in Claims 19-21. Thus, this rejection should be rendered moot.

Accordingly, Applicants respectfully request that the rejection of Claims 19-21 under 35 USC §112, first paragraph be withdrawn.

Rejection of Claims 1-31 under 35 USC §112, first paragraph

The Examiner has rejected Claims 1-31 under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner stated that:

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for non-heterocyclin substituted 1,2,9,9-tetrahydro-3H-fluoren-3-ene compounds, does not reasonably provide enablement for compounds containing heterocycloalkyl, heteroaryl, heteroarylalkyl etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. There is insufficient disclosure of starting material to place such a genus of compounds in possession of the public in the event of a patent grant. In re Focci 169 USPQ (1971). In addition, the unlimited scope of compounds encompassed by the above terms would require more than routine experimentation as per e.g. Ombruster 185 USPQ 152(1975), and In re Angstadt & Griffen 1990 USPQ 704 (CCPA 1970) wherein routine experimentation, was defined by the late Judge Rich as 8 hours or one working day. In the present use more than one day would be necessary.

Applicants respectfully traverse this rejection. Applicants assert that the specification does enable the claims and provides ample guidance as to how substituted heterocyclic derivatives are prepared.

A claim which covers compounds which are structurally closely related requires a more limited supporting disclosure than a claim covering compounds which are related only in some structural aspects. *See, In re Cavallito et al.* (CCPA 1960) 282 F2d 363, 127 USPQ 202. Applicants submit that the heterocyclic derivatives at issue are closely structurally related to the other tetrahydrofluorenones within the scope of the instant application. Thus, a *limited*

*supporting disclosure* is required. Applicants have provided ample supporting disclosure in the eight generic schemes, thirty-five working examples, and characterization data for over 100 compounds. One skilled in the art, after reading the disclosure in the present application, would be able to make and use the compounds and compositions encompassed by the claims, including heterocyclic derivatives.

Also, Applicants disagree with the Examiner's definition of "routine experimentation" as 8 hours or one working day because that definition does not reflect the current state of the law. Rather, a disclosure is enabling, even if considerable amount of experimentation is involved, if it is *merely routine*, and *not unduly extensive*. See, *Ex part Foreman et al.* (BPAI 1986) 230 USPQ 546. Even though some experimentation may be necessary to practice certain embodiments covered by the claims, the claims will be found commensurate with the scope of enabling disclosure in the specification if the amount of experimentation required of a person of ordinary skill in the art is found reasonable under the circumstances. In the instant application, Applicants submit that the heterocyclic derivatives can be prepared by a person of ordinary skill in the art given the knowledge of synthetic methodology and starting materials in the art at the filing date. The synthesis of said heterocyclic derivatives is both routine and not unduly extensive.

Accordingly, Applicants respectfully request the rejection of claims 1-31 under 35 USC §112, first paragraph, be withdrawn. Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

If a telephonic communication with the Applicants' representative will advance the prosecution of the instant application, please telephone the representative indicated below. Applicants believe no additional fees are due but the Commissioner is authorized to charge any fees required in connection with this response to Merck Deposit Account No. 13-2755.

Respectfully submitted,

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